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<p>(21) International Application Number: PCT/US84/01852</p> <p>(22) International Filing Date: 8 November 1984 (08.11.84)</p> <p>(31) Priority Application Number: 564,519</p> <p>(32) Priority Date: 22 December 1983 (22.12.83)</p> <p>(33) Priority Country: US</p> <p>(71)(72) Applicant and Inventor: KAMEN, Dean, L. [US/US]; 44 Gage Road, Bedford, NH 03101 (US).</p> <p>(74) Agents: SUNSTEIN, Bruce, D. et al.; 31 Milk Street, Suite 810, Boston, MA 02109 (US).</p> <p>(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), JP, LU (European patent), NL (European patent), SE (European patent).</p>		<p>Published <i>With international search report.</i></p>
<p>(54) Title: CATHETER STABILIZATION PAD</p> <div data-bbox="535 1234 1120 1795" data-label="Image"> </div> <p>(57) Abstract</p> <p>A unitary sheet device (1) for removably securing a catheter (6) to the skin of a patient includes a pair of flaps (3) for being affixed to the skin and a central portion (4) preformed in a contour conforming to the catheter hub. When affixed, the central portion (4) and the patient's skin together form a receptacle for securely holding the catheter against movement. The central portion (4) may be a tapered conical sheet and the flaps (3) may have adhesive for ease of attachment. A detent (8, 21) is provided, which may include a hole (8) through the central portion (4) of the sheet for engaging a protruding hub (21) from the catheter hub. Flexing of the sheet disengages the detent elements (8, 21). A non-adhesive tab (5) on one flap (3) aids in removing the device (1).</p>		

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CATHETER STABILIZATION PAD**DESCRIPTION****Technical Field**

5 The present invention relates to methods and devices for holding down an infusion catheter to prevent unwanted motion of such catheter when attached to the body of a patient, and more particularly to such a device which
10 allows detachment of the catheter from the body of the patient without requiring prior removal of the device.

Background Art

15 It is common hospital practice to administer medicines or other fluids to a patient via an infusion tube attached to an intravenous needle or catheter attached to a patient's limb. The needle or catheter must be manually
20 inserted to a precise location, which may be intravenous, intramuscular or subcutaneous, and thereafter this location must be maintained as appropriate for the particular infusion fluid, despite the possible twisting and turning of the patient or the motion of the appended infusion tubing. In practice, the catheter tube or needle extends
25 from a more substantial catheter hub body to which the infusion tubing is attached; the body has a pair of laterally extending flanges which are generally taped to the patient to prevent extraneous motion of the assembly. Because even minor motions of the body could lead to
30 movement of, or pressure on, a needle assembly, it is common to employ a hollow plastic catheter tube as the element which penetrates the skin to deliver the medication. This tube is initially installed by inserting a conventional needle therethrough and puncturing the skin
35 of the patient for insertion, thereafter withdrawing the needle and leaving the infusion tube as a flexible attachment to the patient. This allows a slight amount of



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bending of the tube itself, or motion of the catheter hub body, without breaking or kinking of the flow path, or local trauma caused by wobbling of the needle due to lateral pressure being transmitted. However the taping of a catheter body to the skin of the patient is cumbersome,
5 and the catheter may not be removed from the patient thereafter without removing the tape. It can be traumatic for a patient to have adhesive tape painfully pulled from his skin prior to removal of the catheter.

Several devices have been patented for holding such an
10 assembly in a stable position. Thus the device of U.S. patent no. 4,129,128 shows a hold-down device with a pair of wings and a central housing, wherein the wings may be taped securely to the body of a patient and the central housing has end walls adapted to receive the laterally
15 extending "ears" of a catheter hub. U.S. patent no. 3,900,026 shows a rigid rectangular box-like structure, with a flexible neck which engages the catheter hub, the whole rectangular housing forming a protective shield for the needle and being secured to the body of a patient by an
20 adhesive flange extending around the perimeter. Neither of these devices appears to permit removal of the catheter from the patient's body without prior removal of the hold-down device. There is thus a need for a simple catheter stabilization device capable of securely holding a
25 catheter against unwanted movement yet allowing release of the catheter and removal thereof from the patient without requiring prior removal of the stabilization device.

Brief Description of the Invention

30 The present invention is a flexible catheter stabilization device formed of sheet material having a pair of laterally protruding flaps on either side of the axis defined by the catheter, and connected by a central portion
35 having a contour for receiving the body of the catheter hub. In a preferred embodiment, the contour is tapered and a hole or detent in the central portion engages a



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corresponding element of the catheter hub to prevent motion of the catheter assembly along the axis defined by the catheter tube. In a further preferred embodiment the tapered central portion is of conical shape, and pinching the flaps together releases the hub so it may be withdrawn without removing the stabilization pad from the body of the patient. An adhesive band around the perimeter of the flaps on the lower side thereof permits easy application of the pad to the patient, in an adhesive tape-like fashion, after the catheter has been inserted. A non-adhesive tab on one flap aids in gripping the pad for removal after use. A beveled edge portion provides greater flexibility and compliance of the adhesive perimeter of the flaps, for more secure attachment to contoured surfaces. These and other features of the invention will be more readily understood by reference to the drawings.

Brief Description of the Drawings

Figure 1 shows a top view of the catheter stabilization pad according to the present invention;
Figure 2 shows a side view thereof;
Figure 3 shows a front view from the catheter end of the present invention;
Figure 4 shows a perspective view of the pad adhered to the limb of a patient;
Figure 5 shows a catheter and hub with detent adapted to the pad of Figure 1; and
Figure 6 shows a bottom view of the catheter and hub of Figure 5.

Description of Specific Embodiments

Referring to Figure 1 there is shown a basic embodiment of the stabilization pad 1 of the present invention, having flaps 3 disposed on either side of a central portion 4. The unit may be made of a molded polyethylene, or vacu-formed from sheet stock of any



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appropriate flexible plastic. As shown, central portion 4 is adapted to receive the hub 4 of a catheter (shown in phantom) having a catheter tube 6 extending therefrom. Also shown in Figure 1 is an aperture 8 in the central portion 4 for receiving a corresponding detent or protrusion from the catheter hub and holding the hub secure against axial motion. The perimeter portion 9 of the stabilization pad is preferably treated with an adhesive on the underside thereof so that the pad may be applied like a self-adhesive bandage without requiring external taping or straps to hold it securely on the body of the patient. A tab 5, not having adhesive thereon, but protruding from one wing, serves as a grip to aid in removal of the stabilization pad. As may be seen, the two flaps 3 extend on either side of the catheter body and are approximately symmetrically disposed in relation to the axis defined by the catheter tube 6.

Turning now to Figure 2, it may be seen that the axis 20 defined by the tube 6 is a central axis of the the catheter hub 2. It is conventional for a catheter hub to have a central bore, into which a needle is inserted to stiffen and stabilize the flexible plastic tube 6 to permit insertion thereof through the skin of a patient. Also conventional catheter hubs generally have the external profile of a slightly tapered cone. Such a profile allows the hub body to rest in a position approximately tangential to the skin of the patient when the needle has been inserted, at an angle, to an appropriate depth. In the present device, advantage is taken of this conical profile by providing a contoured tapered sheet surface as the central portion 4, which conformably fits against the profile of the catheter hub. As shown, the central portion 4 narrows as it gets closer to the catheter tube end of the hub. Also shown in Figure 2 is a nub 21 projecting upward from the body of the catheter hub and through the aperture 8 of Figure 1. The stabilization pad itself is formed of a flexible but relatively thick sheet. The top surface thereof, around the edges 9 of Figure 1, is beveled as



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shown at 23 in Figure 2, thus effectively thinning the edge portion and permitting a greater pliability in that area. The underside of beveled surface 23 bears an adhesive layer 22 for attaching to the body of a patient. The adhesive need not extend entirely around the perimeter, and indeed, where it is desired to remove the catheter without first removing the pad, it is advisable to omit the adhesive near the central regions of the pad so that the "ears" appearing on a normal catheter may easily slide under the perimeter portion thereof for removal.

Turning now to Figure 3, there is shown an end view of the stabilization pad according to the present device in which the flaps 3 at each side attach to the center portion 4 which conformally wraps around the catheter hub 2. The protruding nub 21 may be seen projecting up through the sheet of the center portion 4.

Figure 4 shows a catheter stabilization pad according to the present invention in use, with infusion tubing or inlet connection tubing 41 leading into the hub and catheter tube 6 extending from the front of the hub through the skin of the patient. It will be appreciated that the taper of the central portion permits the catheter to slide into a secure position and subsequently be retained there as the protruding nub 21 reaches the retaining aperture 8 thereby locking the hub into position. As the catheter is inserted there becomes progressively less looseness for maneuvering the hub and upon full insertion the hub is firmly held on all sides against motion. The laterally projecting hub "ears" shown in phantom prevent any twisting of the hub which could cause kinking of the inlet tube or of the catheter tube 6. The conformable contour of the central portion prevents any lateral motion whatsoever; and the detent system comprising the aperture 8 and nub 21 prevents any axial motion. In this manner, the catheter stabilization pad provides an unprecedented degree of stability of the catheter itself. Nonetheless, in the event it is desired to remove the catheter from the body of the patient, as for instance upon discharge, or simply to



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employ a different vein for the infusion, the catheter hub may be released from the stabilization pad by simply pinching together the skin of the patient in the area of the two wings, thus causing the central portion to rise up releasing the nub 21 and allowing the withdrawal of the hub from the central portion along axis 20. The stabilization pad itself is not situated over the actual site of needle insertion, and therefore may be left in place without worry of infection or other consequences until such time as it may be removed without trauma to the patient. In this manner the association of physical pain with the insertion or removal of needles or catheters is entirely avoided, thus eliminating one of the common negative experiences of modern hospital practice.

Turning now to Figure 5, there is shown a detailed view of the catheter employed with the present stabilization pad. As noted above, the pad itself is generally adapted or adaptable to common catheters currently used, requiring in addition only a detent or projection, like nub 21, to provide the axial stability of the invention. Such a catheter is shown having flexible catheter tube 6 extending from a tapered hub 52. Hub 52 has a pair of laterally extending wings 51 of relatively small dimension which define a plane at the bottom thereof which rests against the skin of the patient and serves to prevent rotation of the hub 52 in use. Extending from the top of hub 52 is a nub 21 in the form of a straight tab. It is clear that nub 21 may be of virtually any shape so long as it mates with the corresponding aperture 8 of Figure 1 so as to prevent motion along the catheter axis 20. Similarly wings 51 may be quite small. Unlike the "ears" of a conventional catheter, they need not be taped to the body but serve only the residual purpose of providing a flat orientation against the skin. Similarly, tapered hub 52 may be of virtually any cross-sectional shape, such as a long thin pyramidal shape and need not be conical. The purpose of the taper, in addition to the conventional function of defining a guide for the needle



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used in inserting tube 6 through the skin, is largely to allow progressively more secure insertion of the body within the stabilizing central portion 4 of the stabilization pad. At the rearmost edge of the catheter hub is flange 42, which extends a slight distance radially outward so as to butt against the edge of the stabilization pad and provide a well-defined stop to limit insertion. While the use of nub 21 and aperture 8 suffices to axially secure the device, the flange 42 adds further restraint against wobble.

Turning now to Figure 6, there is shown a bottom view of the catheter of Figure 5. As may be seen, the lower portion 63 of body 52 is flat and forms a common plane with wings 51 so as to rest on the skin of the patient without twisting. Lower edge of flange 42, which would only bear against the skin of the patient, is removed.

It will be appreciated that the precise shape of wings 51 is of little importance, as long as they project somewhat laterally to prevent twisting of the device, and the invention may be practiced altogether without such wings, if lower surface 63 of the catheter body is of sufficient size to assure that the hub 4 does not rotate. However, in the event wings 51 are used, it will be appreciated that a portion of the stabilization pad 1 located adjacent to the central portion should not have any adhesive in a location which would interfere with withdrawal of the catheter from the stabilization pad.

In one embodiment of the invention, wings 51 measure 1/2 inch (13 mm), tip to tip, and the catheter hub is approximately 3/16 (5 mm) of an inch in diameter at its large end. The stabilization pad itself measures 2 1/4 inches (56 mm), side to side, with a maximum front to back dimension of 1 1/2 inches (38 mm) and has a beveled peripheral region 1/16 of an inch (1 1/2 mm) wide. The catheter hub is 3/4 inches (19 mm), tip to tip, and both the rear flange 42 and the nub 21 extend approximately 1/32 (.75 mm) of an inch and have a thickness of approximately .040 inches (1 mm). The stabilization pad provides a high



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degree of stability and comfort, isolating the catheter tube from the incidental motions of the infusion tube 41.

It will be appreciated that the present invention requires no rigid housing and presents an elastic structure which can removably engage a catheter hub so as to permit sanitary and simple maintenance of the hub in position yet allow convenient removal as needed, without any trauma upon removal. It will be appreciated that the invention may readily be practice with a wide variety of flexible plastic or rubber-like material; it may be practiced with adhesive or non-adhesive flaps, in which case the flaps may be attached with adhesive tape as in a conventional catheter hub. The taper of the central portion may conveniently be of any shape adapted to fit the catheter hub so long as the pad and hub together have a detent means for preventing axial motion after insertion. Similarly the detent may include any means of mating protruding elements, preferably of an aperture and nub variety, which may be released by squeezing together the wings of the pad in such a way as to cause the central portion to flex away from the catheter hub. Accordingly, the invention is limited only by the following claims.

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What is claimed is:

1. The combination of a catheter, having a hub and a catheter tube extending therefrom, with a stabilization pad for securely holding the catheter to the body of a patient, the pad comprising:

flexible sheet means, including a central contoured portion and a pair of laterally extending flap portions disposed on either side of the central portion, for being affixed to the skin of the patient, wherein the central portion is preformed with a contour substantially conformal to the external profile of the catheter hub, so that when the flap portions are affixed to the skin of the patient the central portion forms a receptacle for securely holding the catheter hub against movement.

2. The combination of claim 1, wherein the hub has a tapered external profile and the contoured central portion of the sheet is of a substantially identical contour, tapering from a large cross-section at one end to a smaller cross-section at the other end, so that the catheter may be conveniently removed by moving it toward the larger end without removing the sheet from the body.

3. The combination of claim 2, wherein the hub has a central axis defined by the catheter, and also includes a stop member, projecting from the hub radially outward from the axis, for engaging the sheet to prevent axial motion of hub with respect to the sheet when disposed in the receptacle.

4. The combination of claim 3, wherein the tapered profile of the hub and the central portion is a conical tapered profile.

5. The combination of claim 3, wherein the stop member is located centrally on the body of the hub, and the central portion of the sheet has an aperture extending entirely therethrough for snugly receiving the stop member and securing the hub against axial motion within the receptacle.

6. The combination of claim 3, wherein the hub further includes a second stop member projecting radially



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outward with respect to the axis and axially spaced apart from the first member, and wherein the central portion is of a width so that opposing edges thereof are sandwiched between the two stop members, preventing relative axial motion of the hub and the sheet, when the hub is in the
5 receptacle.

7. The combination of claim 3, wherein the sheet further includes adhesive means, on one surface of each flap, for adhering the device to the body of a patient.

8. The combination of claim 7 wherein the sheet
10 further includes tab means, at the periphery of a flap, for use as a grip in pulling the pad off the patient after use.

9. A stabilization device for attachment to the body of a patient to securely hold a catheter hub against
15 motion, such device comprising:

a unitary flexible sheet, having a contoured central portion and a pair of laterally extending flap portions, for being affixed to the skin of the patient, on either side of central portion, wherein the central portion is
20 preformed with a contour substantially conformal to the surface of the catheter hub, so that when the flap portions are affixed to the skin of the patient the central portion, together with the adjacent surface of the patient, forms a receptacle for securely holding the catheter hub against
25 motion.

10. A stabilization device according to claim 1, wherein the central portion includes an edge for engaging a protrusion of the catheter hub so as to prevent axial motion of the hub in the receptacle, and wherein the sheet
30 is sufficiently flexible that appropriate bending of the flaps may cause the edge to disengage from the protrusion.

11. A stabilization device according to claim 10, wherein the surface of the catheter hub and the contour of the central portion are a surface of revolution about an
35 axis.

12. A stabilization device according to claim 11, wherein the flap portions include adhesive means disposed



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on one side thereof for affixing the flap portions to the skin of the patient.

13. A stabilization device according to claim 12, further including a hole extending entirely through the sheet at the central portion thereof, such hole being located so that its edge engages the protrusion of the hub to prevent axial motion.

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FIG. 1

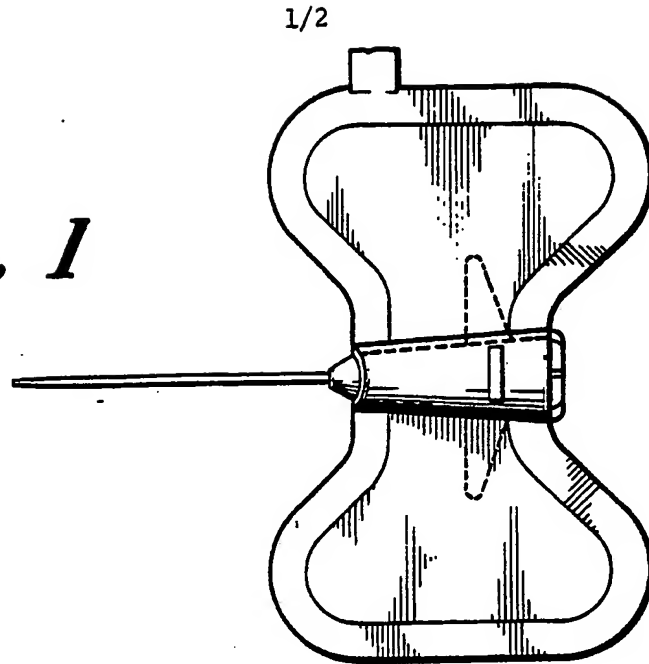
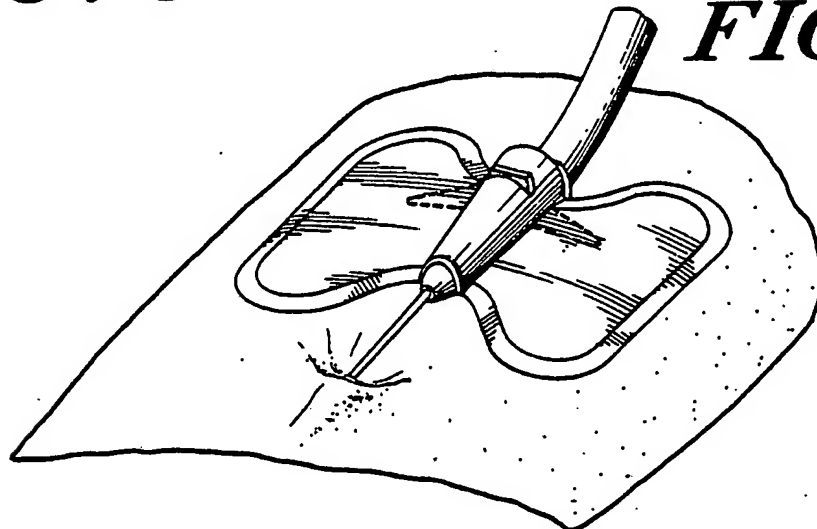


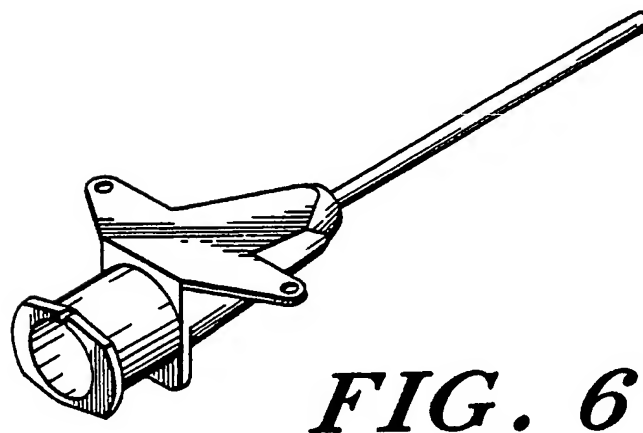
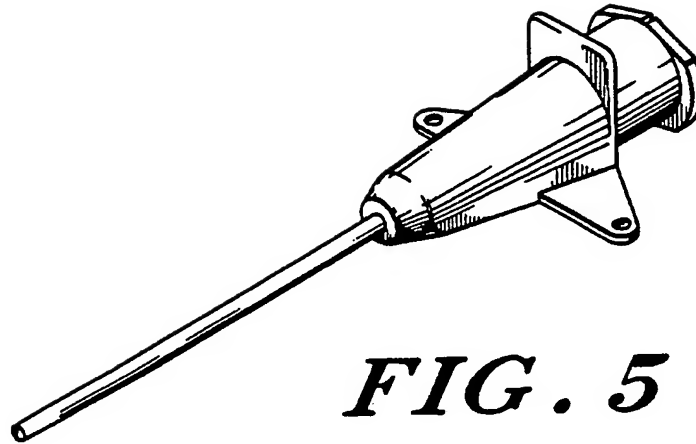
FIG. 2



FIG. 3

FIG. 4





INTERNATIONAL SEARCH REPORT

International Application No PCT/US84/ 01852

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ¹		
According to International Patent Classification (IPC) or to both National Classification and IPC Int. Cl. 3 A61M 5/00, A61M 25/00 US cl 604/177		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁴		
Classification System	Classification Symbols	
US	128/Dig 26, 128/133, 604/164-165, 604/174, 177, 179-180	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched ⁵		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴		
Category ⁶	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
EX	US, A, 4,484,913 27 November 1984 SWAUGER	1-13
PX	US, A, 4,445,893 1 May 1984 BODICKY	1-13
A	US, A, 4,392,856 12 July 1983 LICHTENSTEIN	
Y	US, A, 4,366,817 4 January 1983 THOMAS	1-9
A	US, A, 4,250,880 17 February 1981 GORDON	7,8,12
Y	US, A, 4,129,128 12 December 1978 MCFARLANE	1,9
A	US, A, 3,834,380 10 September 1974 BOYD	
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>¹⁵ * Special categories of cited documents: ¹⁵</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
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